K090567

MAY 27 2009

510(K) SUMMARY

[as required by 807.92(c)]

1. Identification of the Device:

   -Proprietary-Trade Name: "Orthodontic Ceramic Bracket (ABSOLUTE)" Star Dentech Korea., Corp.
   -Classification Name: bracket, ceramic, orthodontic, Product Code: NJM
   -Common/Usual Name: Orthodontic Ceramic Bracket / Orthodontic Ceramic Bracket

2. Equivalent legally marketed device:

   This product is similar in design and identical in function to the K073045 / SAPPHIRE CERAMIC BRACKET / ORTHO TECHNOLOGY, INC

3. Indications for Use (intended use):

   Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth

4. Description of the device:

   Orthodontic Ceramic bracket, "ABSOLUTE" is made of alumina single crystal (mono clean sapphire) intended to be placed on teeth to straighten teeth. ABSOLUTE ceramic bracket consists of 3 parts. The first part is slot part is a way for orthodontics wire. The second part is round groove part that is to hold a wire with elastic "O" ring.
   And, the third part is base part is to adhere to tooth surface. Also, it has a marking on fore surface to indicate a location.

5. Testing information and Conclusion

   In all material respects, the "Orthodontic Ceramic bracket (ABSOLUTE)" is

substantially equivalent to SAPPHIRE CERAMIC BRACKET (K073045) ORTHO TECHNOLOGY, INC. Testing was performed according to 'Harmonized Standard'. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Star Dentech Korea, Corporation
C/O Mr. Brandon Choi
General Manager
Pats Corporation
49 Candlewood Way
Buena Park, California 90621

Re: K090567
Trade/Device Name: Orthodontic Ceramic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: February 14, 2009
Received: March 3, 2009

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090567

Indications for Use

510(k) Number (if known):

Device Name: Orthodontic Ceramic Bracket

Indications for use: Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090567